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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,989	09/18/2000	Robert Charles Susil	55106 (71699)	4542
21874	7590	05/19/2005		
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205				
			EXAMINER JUNG, WILLIAM C	
			ART UNIT 3737	PAPER NUMBER

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/663,989

Applicant(s)

SUSIL ET AL.

Examiner

William Jung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments with respect to claims 1-44 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7, 10-21, 23, 30-34, 37-42, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by **Bucholz** (US 5,871,445).

Bucholz anticipates all claimed features in claims 1-44.

**Claims 1, 14-21, 23, 31-34, 40, 41, 42, and 44:** Bucholz discloses a system and method of imaging cross-section of a patient to track the position of an invasive probe placed within a body by simultaneously imaging the probe with respect to fiducial markers RP1, RP2, and RP3. The markers provide reference coordinate in which the imaging apparatus and method obtains cross-sectional images that includes the invasive probe and fiducial markers to give reference point to guide the probe to a desired location by manipulating the probe within the body related to the image coordinate system (col. 1, line 36 – col. 2, line 25; col. 5, lines 3-34; col. 6, lines 25-41).

**Claims 2-4 and 30:** Bucholz discloses that the fiducial markers in the image is unique for the pose or the location of the invasive instrument where the surgical probe

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(therapeutic instrument) is identifiable to the reference coordinate within the therapeutic field or region interest within the image (col. 6, lines 25-41).

**Claims 5-7:** The above process and apparatus includes determining the position of the probe based on the detected image space (col. 6, lines 25-41).

**Claim 10:** Bucholz's invasive probe device 542 shown in figure 4A where a handle portion 540 is clearly provided for the surgeon to manipulate the device.

Although the written disclosure is silent as to manual manipulation, it is inherent that the handle is used manually.

**Claims 11, 12, 37, and 38:** Bucholz also discloses that software is used to determine the trajectory of the probe's coordinate along with translational mechanics to manipulate the surgical instrument. Although, Bucholz's disclosure does not specifically state robotic arms, the functional mechanics of Bucholz's device is equivalent to robotic arm (col. 3, lines 7-64).

**Claim 13 and 39:** Bucholz disclose in the background of the art that the 3D imaging system such as CT, MRI, PET, EMG, or ultrasound is used to acquire the images disclosed above to track the position of the invasive probe (col. 1, lines 9-23; col. 1, lines 36-47).

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 8, 9, 22, 35, 36, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Bucholz*.

**Claims 8, 9, 35, 36, and 43:** The shape of the fiducial motif is unique in a sense to the imaging system since the markers must provide unique or differential point in which the markers are indicative of the coordinates. As shown by Bucholz in figure 2, the markers RP1, RP2, and RP3 are orthogonal in relation to each other in space to provide 3D coordinate system in which the surgical instrument can be tracked. The shape of the marker whether it is N shaped or U shaped is inconsequential to the imaging system since the markers must be unique to the imaging system. Therefore, the shape of the markers is design choice.

**Claim 22:** The timing of the image acquisition as claimed in claim 22 is design choice as well. The image acquisition time and interval period are dictated by the surgical procedure, therefore the image time period is a design choice.

6. Claims 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Bucholz* as applied to claim 16 above, and further in view of *Gilles et al* (US 6,272,370).

Bucholz substantially discloses all claimed features in claims 24-29. However, Bucholz only discloses the surgical tool in general and does not include limitations of delivering therapy process. In Gillies et al's invention, a stereotactical device such as needle biopsy is used with CT or imaging system as guidance to a target location where the drug delivery or depositing of therapeutical material is performed. In addition, Gillies et al also disclose application of heat or energy as therapy method. Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of Gillies et al's therapeutic injection via invasive tools such

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as needle biopsy to Bucholz's method described above to achieve the claimed invention in claims 24- 29.

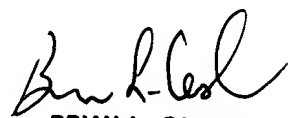
*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*WJ*  
May 13, 2005

  
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